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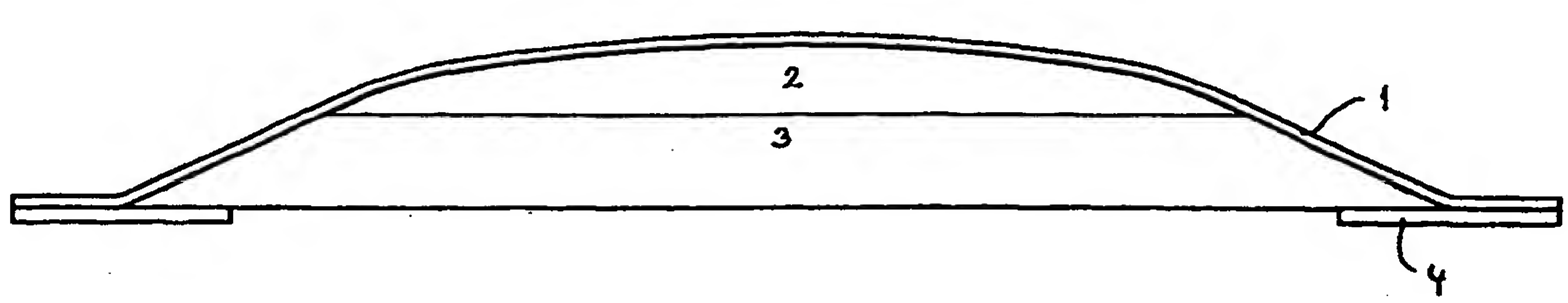

(57) Abstract: A device for treating a skin site or for promotion of healing of a wound site at an exposed surface of the skin of a human being by providing carbon dioxide at the exposed surface of said skin site or wound, said device comprising a top layer, means for generating carbon dioxide in situ and a skin-contacting layer.

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TITLE

A carbon dioxide generating device

FIELD OF THE INVENTION

The present invention relates to a device for treating a skin site or for promotion of healing of a wound site at an exposed surface of a human being by providing carbon dioxide at the exposed surface of said skin or wound site.

BACKGROUND OF THE INVENTION

The use of gas treatment of the body or body parts for medical or therapeutic purposes is well known.

GB patent Application No. 2 024 012 discloses an oxygen generating surgical dressing. The dressing comprises a hydrocolloid sheet impregnated with a composition being capable of generating oxygen when contacted with an activator. This contact is established e.g. by removing a release liner and contacting two surfaces.

US Patents No. 5 788 682 and No. 5 578 022 disclose an oxygen generating wound dressing. In both cases the oxygen is generated in an electrochemical cell. The reference is only regarding oxygen as a gas.

The use of oxygen in the treatment of wounds may however give rise to problems, as prolonged use as well as use of large doses may cause toxic effects in the tissue.

Carbon dioxide baths have been used in the treatment of circulatory diseases for more than hundred years. The CO_2-gas, being dissolved in the water of such baths, diffuses into the blood of the capillary system through the dermal layers of the skin. This diffusion is possible as CO_2 is soluble in both the aqueous and the fatty components of the skin.

The beneficial effects of carbon dioxide is in the form of the Bohr effect as well as a vasodilatory effect. An increased amount of locally dissolved CO_2 in the blood will lead to a decrease in the pH of the blood. This decrease in pH results in a decrease in the haemoglobins ability of binding oxygen, and hence an increased amount of oxygen is released locally in the tissue (the Bohr effect). The vasodilatation, a local dilation of the capillary system, causes an increased blood flow and thus increases the oxygen supply to the tissue.

An enhanced micro circulation and increased tissue oxygenation will help to improve the overall condition of the wound tissue by supplying oxygen and nutrients and removing waste products thus creating better conditions for wound healing.

A well known treatment with CO_2 is in the form of baths, in which the water contains between 400 and 4000 mg CO_2 per liter water. Pure CO_2-gas may also be used, e.g. by wrapping the treated body part or the whole body in a gas tight bag and supplying this bag with gas from an external source.

Japanese patent application No. 11-47219 discloses a carbon dioxide plaster for local treatment with the gas. The plaster is used during bathing. The plaster comprises two layers, a carbon dioxide generating layer, wholly or partly covered with an adhesive layer on the skin-contacting side of the plaster. The carbon dioxide generating layer is in the form of a dry tablet, which when contacted with water during bathing will generate CO_2 in the area of the plaster, which may be mounted on a body part such as a shoulder. The reference is silent with respect to the gas permeability of the adhesive as well as no cover film to diminish the escape of the gas from the treated area is mentioned.

DE patent application No. 37 17 582 discloses a CO_2-treatment comprising an airtight bag surrounding the selected body part, e.g. the leg or foot, into which bag is lead CO_2 from an external source. The treatment is for cosmetic, relaxing or sexual stimulating purposes. Obviously, the treatment will be difficult to perform on a patient unless he is confined to a bed or otherwise immobilised during the treatment.

DE Utility Model No. 298 20 187 is claiming a portable gas treatment device comprising a suitcase containing a gas-cylinder with carbon dioxide and flexible tubes leading from the gas-cylinder to the body part being treated. The body-part is wrapped in a gas tight bag and the gas is lead into the bag from the cylinder in the suitcase. The device may be portable, but not particularly handy, as the patient has to carry a heavy suitcase with him during the treatment.

In FR patent application No. 2 656 218 is disclosed a device for local treatment with a gas such as oxygen, nitrogen or carbon dioxide. The body-part being treated may be encapsulated in a bag or covered with a dressing comprising a cover film and a dressing part. A tube is leading gas from a gas supply into the bag/dressing in a regulated manner.

Very few references refers to wound care treatment with carbon dioxide, but the positive effects of the treatment ought to be even better in the wound treatment because of the missing skin barrier.

None of the above mentioned references disclose truly portable carbon dioxide-donating devices, as most of them involve an external gas supply, as well as they involve unhandy bandages or bags in which the treated body part is wrapped. It is desired to have a portable device with an integrated gas supply, and a handy size, e.g. the size of an ordinary wound dressing.

Thus, there is still a need for a non-toxic, handy device for treating a skin site or for promotion of healing of a wound site by providing carbon dioxide in situ to the exposed site.

BRIEF DESCRIPTION OF THE INVENTION

The invention relates to a device for treating a skin site or for promotion of healing of a wound site at an exposed surface of the skin of a human being by providing carbon dioxide at the exposed surface of said skin site or wound, said device comprising a top layer, means for generating carbon dioxide in situ and a skin-contacting layer.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings in which:

Figure 1 shows a cross-section of an embodiment of the invention.

Figure 2 shows a cross-section of another embodiment of the invention.

Figure 3 shows a top view of yet another embodiment of the invention.

Figure 4 shows the principles of an electrochemical cell.

Figure 5 shows a cross-section of an embodiment of the invention.

Figure 6 shows a cross-section of another embodiment of the invention.

Figure 7 shows a top view of the embodiment of Figure 6.

Figure 8 shows a cross-section of yet another embodiment of the invention.

Figure 9 shows a top view of a still further embodiment of the invention.

Figure 10 shows a top view of an embodiment of the invention.

Figure 11 shows a detail from Figure 10.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a device for treating a skin site or for promotion of healing of a wound site at an exposed surface of the skin of a human being by providing carbon dioxide at the exposed surface of said skin site or wound, said device comprising a top layer, means for generating carbon dioxide in situ and a skin-contacting layer.

In a preferred embodiment of the invention the device is a wound dressing.

The carbon dioxide-generating means in the device according to the invention may preferably comprise means for controlling the gas generation.

The generation of carbon dioxide may suitably be extended over a period of time for establishing a longer period of relatively constant treatment.

According to the invention, the carbon dioxide may alternatively be delivered discontinuously or in peaks or pulses enabling a controlled treatment according to a desired pattern of higher and lower concentrations of carbon dioxide.

In a first embodiment of the invention the device comprises a wound contacting layer being capable of absorbing wound exudate. This wound contacting layer may be a layer of foam, hydrocolloid, hydrogel, polymer gel, alginate or another skin-friendly absorbing material. The layer may constitute all of the skin-contacting surface, or only a part thereof. The layer may comprise an adhesive.

A skin-friendly adhesive may cover all of the proximal wound contacting surface or only a part thereof and may be any skin-friendly adhesive known per se, e.g. an adhesive comprising hydrocolloids or other moisture absorbing constituents for prolonging the time of use. The adhesive may suitably be of the type disclosed in GB patent specification No. 1 280 631, in DK patent specifications Nos. 127,578, 148,408, 154,806, 147,226 and 154,747, in EP published application Nos. 0 097 846 and 0 415 183, in SE published application No. 365,410, in WO publication No. 88/06894, in US patent specification No. 4,867,748, and in NO published application No. 157,686. Especially preferred are the adhesives disclosed in US patent Nos. 4,367,732 and 5,051,259 and DK patent specification No. 169,711.

Other suitable adhesives may be constituted by a wide range of different types of adhesives for instance the acrylic types, and types derived from PIB, polyurethanes, EVA-compounds, APAO's, silicones, polyvinyl ether etc.

The device according to the invention may be covered on the non-skin-contacting surface with a top layer, e.g. a foam, a non-wowen, or a film, such as a polyurethane film. The top layer may preferably serve as a barrier for the gas, thus raising the partial pressure of CO_2 over the wound.

In a preferred embodiment of the invention the top layer is substantially impermeable to carbon dioxide.

In a second embodiment of the invention the top layer extends beyond the edge of a pressure distributing element defining a flange around the device. The flange may optionally be covered with an adhesive, defining an adhesive framing.

The top layer may be of any suitable material known per se for use in the preparation of wound dressings e.g. a foam, a nonwoven or a polyurethane, polyethylene, polyester or polyamide film. The top layer may be water impervious or permeable for water or it may be of a type having a higher water permeability when in contact with liquid water than when not in contact.

A suitable material for use as a top layer is a polyurethane. A preferred low friction film material is disclosed in US patent No. 5,643,187.

In a third embodiment of the invention the CO_2-generating means comprises at least one chemical composition being capable of generating carbon dioxide when activated.

Such chemical compositions may be any well known chemical composition known per se being capable of releasing carbon dioxide.

Examples of such chemical compositions being able to release gaseous CO_2 are combinations of an acid and a carbonate which, when mixed, will react according to the below and release CO_2:

$$CO_3^{2-}\,(aq) + 2\,H^+\,(aq) \longrightarrow CO_2\,(g) + H_2O$$

The acid may be an inorganic or an organic acid such as tartaric acid, lactic acid, citric acid, succinic acid, fumaric acid, malic acid, benzoic acid or any other suitable acid.

The carbonate may be an alkali metal carbonate or an alkaline earth metal carbonate such as calcium carbonate, sodium carbonate, sodium hydrogen carbonate, magnesium carbonate, potassium carbonate, potassium hydrogen carbonate or any other carbonate such as ammonium carbonate.

Another way of producing gaseous CO_2 is by heating a carbonate e.g. sodium hydrogen carbonate or another suitable carbonate:

$$2\,NaHCO_3\,(s) + \text{heat} \longrightarrow Na_2CO_3\,(s) + CO_2\,(g) + H_2O$$

Yet another way of producing gaseous CO_2 is by fermentation, e.g. of sugar:

$$C_6H_{12}O_6 \dashrightarrow 2\ C_2H_5OH\ (l) + 2\ CO_2$$

The chemical compositions may be present in dry or in liquid form. If they are present in liquid form they may have to be stored separately in the device, to avoid reaction before use and during storage. If the chemicals are present in a dry form, the components may be mixed.

In a fourth embodiment of the invention the CO_2-generating compositions are incorporated in the device in the form of a dry powder. This powder may be located on top of the skin-contacting and optionally exudate handling layer and may wholly or partly cover the exudate handling layer.

The reaction leading to the generation of carbon dioxide may be activated in different ways.

If the chemical composition in the CO_2-developing layer is in a dry form, the reaction may be activated by uptake of water or moisture. The moisture may e.g. be wound exudate, but may also be an aqueous liquid such as water being added right before application of the device or it may be an aqueous liquid such as sterile water or isotonic saline being trapped in inclusions or encapsulations in the device. These inclusions or encapsulations may be broken, and thereby releasing the aqueous liquid to contact the CO_2 releasing composition, e.g. by adding mechanical pressure to the device.

In a fifth embodiment of the invention one or more of the chemical components is in the form of a liquid and may be encapsulated in separate inclusions, said encapsulation may be broken by applying a pressure to the device.

In a sixth embodiment of the invention the exudate from the wound may be absorbed by the exudate handling layer, transported through this and be brought into contact with the dry chemical components, and activate a carbon dioxide releasing reaction.

The generation of carbon dioxide may also be activated by heat, irradiation or pressure.

In a seventh embodiment of the invention the carbon dioxide release is activated by heat, or the device may be heated in the hands of the applicant or the body heat of the patient will activate the process. The heat may also be supplied from an external source e.g. a lamp or an electric blanket or by ultrasound or UV or IR light.

The carbon dioxide releasing process may be activated by irradiation or exposure to sunlight or e.g. UV-light, or the process may be induced by removal of the release liner or protection layer, a string, a split or the like.

In a device according to one embodiment of the invention the CO_2-gas released from the carbon dioxide releasing part of the device may diffuse through the exudate handling part by means of a permeable structure, such as holes. The gaseous CO_2 may dissolve in the wound exudate and diffuse to the wound surface.

In an eighth embodiment of the invention the device may comprise detachable parts rendering it possible to change the CO_2-generating part independently and more frequently than the skin-contacting part. For instance, if the CO_2-generating compositions are incorporated in a form of tablets or sheets, these can be replaced without changing the rest of the device and unnecessarily stressing the wound site and the surrounding skin.

In a ninth embodiment of the invention a change of pH induces the carbon dioxide releasing process in the device.

The release of the CO_2 may be controlled in such a way that a specific amount of CO_2 is released during a given span of time, optionally in the form of a constant release during service time of the device.

A way of controlling the release of carbon dioxide is, if the carbon dioxide releasing components are present in the device as discrete zones or reservoirs, is to have these zones/reservoirs disconnected from each other or connected only by a thin connecting capillary delaying the moisture flow from one zone to the other.

The chemical compositions may e.g. be encapsulated in micro encapsulations, micro spheres, coated with one or more layers of a suitable material known per se, e.g. gelatine or wax. If the coating layers on the individual particles varies in thickness, the speed of the uptake of moisture or wound exudate, or exposure to heat or light will lead to a sustained release of the carbon dioxide.

The chemical composition may be encapsulated in brittle micro capsules, which will break when a certain pressure is applied to the device.

In a tenth embodiment of the invention the chemical components in the dry form is pressed into tablets. For obtaining a slow release of carbon dioxide the tablets may comprise adjuvants known in the art for assisting in obtaining a solid structure of a tablet as well as the adjuvants may be able to provide a matrix being capable of providing the sustained release (analogous to the sustained release of medicaments well known in the art of the pharmaceutical industry).

The distribution of chemical components in the device may be random or systematically, e.g. with a graduated concentration from the centre to the edge of the device, or in the direction away from the surface to be treated.

It is preferred that the skin-contacting layer covers the carbon dioxide generating layer to prevent direct contact between the wound or skin and the chemical compositions.

The carbon dioxide generating means may comprise layers of paper, cloth, non-woven, gauze or alginate impregnated with the chemical compositions.

In a eleventh embodiment of the invention the carbon dioxide-generating means generates carbon dioxide electrochemically.

In a twelfth embodiment of the invention the device may comprise an electrochemical element that generates/concentrates CO_2 from the air or from a carbonate-rich electrolyte. The electrochemical cell may be driven by batteries, solar cells or other energy forming means.

Electrochemical cells may be capable of extracting gases, e.g. CO_2, from the surrounding atmosphere and generating/concentrating the gases, e.g. CO_2, to the other side of the electrochemical cell. An electrochemical cell basically comprises 2 electrodes and an electrolyte. The electrodes and the electrolyte are encased in a casing which is gas permeable but liquid impermeable. The driving force may be a battery, that may be connected through an electrical controller. Atmospheric air or a supplied gas mixture reacts at one electrode, producing one or more reactants which are carried through the electrolyte to the second electrode, where one or more of the former reactants produces the same gases as were extracted from the atmosphere, thereby concentrating the partial pressure of the specific gases.

In a thirteenth embodiment of the invention the device comprises an electrochemical cell capable of generation of CO_2 and O_2 in different ratios, including generation of pure CO_2.

In a fourteenth embodiment of the invention the carbon dioxide-generating means both generates carbon dioxide and oxygen and/or NO_x.

Examples of gas generating electrochemical cells

Example 1 - Generation of CO_2 and O_2 in a ratio 2:1

An electrochemical cell is used comprising an electrode at which oxygen and carbon dioxide is combined with 2 electrons to form carbonate, which is then transported through an electrolyte to the other electrode, where oxygen and carbon dioxide is (re-) generated and 2 electrons are released.

Cathode reaction: $\frac{1}{2}O_{2,cathode} + CO_{2,cathode} + 2e^- \rightarrow CO_3^{2-}$

Anode reaction: $CO_3^{2-} \rightarrow \frac{1}{2}O_{2,anode} + CO_{2,anode} + 2e^-$

Overall reaction: $\frac{1}{2}O_{2,cathode} + CO_{2,cathode} \rightarrow \frac{1}{2}O_{2,anode} + CO_{2,anode}$

The electrodes may comprise a graphite mesh. The electrolyte may comprise an aqueous solution of carbonate. The overall process is reversible and dependent on the direction of the electrical current. The electrolyte pH level is preferably alkaline to ensure a proper concentration of carbonate ions.

Example 2 - Generation of CO_2 and O_2 in a ratio 4:1

An electrochemical cell is used comprising an electrode at which oxygen and carbon dioxide is combined with 4 electrons to form bicarbonate, which is then transported through an electrolyte to the other electrode, where oxygen and carbon dioxide is (re-) generated and 4 electrons are released.

Cathode reaction: $O_{2,cathode} + 2H_2O + 4CO_{2,cathode} + 4e^- \rightarrow 4HCO_3^-$

Anode reaction: $4HCO_3^- \rightarrow O_{2,anode} + 2H_2O + 4CO_{2,anode} + 4e^-$

Overall reaction: $O_{2,cathode} + 4CO_{2,cathode} \rightarrow O_{2,anode} + 4CO_{2,anode}$

The electrodes may comprise a graphite mesh. The electrolyte may comprise an aqueous solution of bicarbonate with a suitable buffer such as phosphoric acid. The overall process is reversible and dependent on the direction of the electrical current. The electrolyte pH level is kept at an optimised level by the use of a buffer, i.e. a pH level, where bicarbonate is present in a proper concentration.

A device according to the invention generating both oxygen and carbon dioxide will enhance the wound healing process in two ways:

The oxygen concentration will increase, enhancing the wound healing processes in the tissue and the carbon dioxide concentration will increase, relaxing the

capillaries in the tissue, leading to an increased transportation rate of blood carrying oxygen and nutrients to the damaged areas.

Example 3 - Generation of CO_2

An electrochemical cell is used comprising a first electrode at which formic acid is decomposed to form carbon dioxide and hydrogen ions under release of two electrons. The ions are transported through the electrolyte (formic acid) to a second electrode. At the second electrode, hydrogen is generated from hydrogen ions under the consumption of two electrons.

Cathode reaction: $2H^+ + 2e^- \rightarrow H_2$

Anode reaction: $HCOOH \rightarrow 2H^+ + 2e^- + CO_2$

Overall reaction: $HCOOH \rightarrow H_2 + CO_2$

In the example formic acid is used as acid. Other useful acids may include acetic acid, oxalic acid, malonic acid and glutaric acid.

By using an external energy source, i.e. inducing a current, the level of acid decomposition may be controlled and as a consequence of this the formation of CO_2 may also be controlled.

The rate of CO_2 generation depends on the external energy source, the availability of the acid and the surface area of the electrodes.

Studies show, that the CO_2 gas generation rate in this example is approximately 0.40cc/mA/h for formic acid and approximately 0.85cc/mA/h for oxalic acid. The purity of the generated gas is in excess of 99%.

The electrochemical cell may be incorporated in the device in a way rendering it possible to be in contact with the atmospheric air, and at the same time donate the generated gas into the device, optionally by placing the cell in the top layer.

The gas may be conducted from the electrochemical cell to a gas reservoir from which the gas diffuses to the wound or skin. This reservoir may be a separate part of the device or it may be a part of the skin-contacting layer where this comprises a porous material, such as foam, capable of storing and transporting the gas.

The electrochemical cell may comprise a connector tube between the cell and the device to prevent new pressure sores.

The connector tube may be wound up around the electrochemical cell which may be placed right next to the device. If the connector tube is needed a sufficient length of tube can be rolled out and the cell can be placed on the body where it will not give rise to any pressure sores.

The electrochemical release of gas may be induced by applying a mechanical force such as a pressure on the electrochemical cell.

The electrochemical cell may be activated in many ways, such as by removal of a slip, by irradiation, an "intelligent" membrane, a computer chip or simply through an on/off button. Means for adjusting the level of generated/delivered gas may also be incorporated. A change of a the battery without changing the device may prolong the use of the device.

In an fifteenth embodiment of the invention the skin-contacting layer may comprise a membrane or "intelligent film" being capable of controlling the gas concentration on the skin side of the device rendering it possible to maintain a defined concentration of gas over the wound. This membrane or film may act as a diffusion barrier.

The gas pressure at the skin side of the device may be controlled by a pressure control membrane or by a pressure membrane which becomes gas permeable at a certain pressure difference between the two sides of the membrane.

The top layer or part of it may be constituted by a pressure sensitive membrane, serving as a valve in case the pressure is exceeding a certain level in the device in order to prevent that a pressure is built up which pressure will cause a slippage of the contact between the device and the skin.

There may be a layer of a porous material, such as foam, between the reservoir where CO_2 is generated and the skin-contacting layer. An open cell foam will serve as a distributor of the generated CO_2.

The CO_2-generating part of the device may be situated over the skin next to the wound to diminish the risk of contact between the CO_2-generating chemicals or the electrochemical cell and the sensitive wound area.

The device may comprise a pressure distributing material, such as a foam, in which an electrochemical cell or a CO_2-generating tablet may be incorporated reducing the risk of generating pressure sores.

The CO_2-generating device according to the invention may be packed in a CO_2-rich atmosphere such as 100% carbon dioxide, or a blend of carbon dioxide and oxygen and or NO_x, in this way the device will be saturated with gas when unpacked for use. If the device comprises a foam, this may be compressed before entering the CO_2-rich atmosphere, where it will expand absorbing the gas insuring a high CO_2-content in the foam.

In a sixteenth embodiment of the invention the device comprises an adhesive skin-contacting layer. To protect the adhesive before use a protective cover or release liner may cover the adhesive part.

A protective cover or release liner may for instance be siliconised paper. The protective cover is not present during the use of the device of the invention and is therefore not an essential part of the invention.

The cover film may optionally be paper, optionally treated with silicone, wax or Teflon, polyethylene terephthalate, high density polyethylene, medium density polyethylene, low density polyethylene, polypropylene, nylon or the like.

Furthermore, the device of the invention may comprise a "non touch" grip known per se for applying the device to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the device either.

It is also advantageous that a device according to the invention comprises wound healing associated indicator(s), cushions or similar device for treatment or prophylaxis of formation of wounds and/or skin abnormalities.

This opens for a combined medical treatment of the wound and an easy and sterile application of the active ingredients, e.g. by incorporating active ingredients such as a cytochine such as growth hormone or a polypeptide growth factor giving rise to the incorporation of such active substances in a form being apt to local application in a wound in which the medicament may exercise its effect on the wound, other medicaments such as bacteriostatic or bactericidal compounds, e.g. iodine, iodopovidone complexes, chloramine, chlorohexidine, silver salts such as sulphadiazine, silver nitrate, silver acetate, silver lactate, silver sulphate, silver-sodium-thiosulphate or silver chloride, zinc or salts thereof, metronidazol, sulpha drugs, and penicillins, tissue-healing enhancing agents, e.g. RGD tripeptides and the like, proteins, amino acids such as taurine, vitamins such ascorbic acid, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, proteinase inhibitors or metalloproteinase inhibitors such as Illostat or ethylene diamine tetraacetic acid, cytotoxic agents and proliferation inhibitors for use in for example surgical insertion of the product in cancer tissue and/or other therapeutic agents which optionally may be used for topical application, pain relieving agents such as lidocaine or chinchocaine, emollients, retinoids or agents having a cooling effect which is also considered an aspect of the invention.

The device of the invention preferably has bevelled edges in order to reduce the risk of "rolling-up" the edge of the device. A bevelling may be carried out

discontinuously or continuously in a manner known per se e.g. as disclosed in EP patent No. 0 264 299 or in US patent No. 5,133,821.

DETAILED DESCRIPTION OF THE DRAWINGS

A cross-section of a preferred embodiment of the invention is shown in Figure 1. The device is covered with a top layer (1), a carbon dioxide generating layer (2) and a skin-contacting layer (3,4) comprising an absorbing part (3) for covering the wound site and an adhesive part (4) at the peripheral part of the device, as an adhesive framing. The absorbing part may serve both as an absorber for wound exudate, a distributor for the carbon dioxide gas and may also serve as a barrier to avoid direct contact between the carbon dioxide generating layer and the skin.

In Figure 2 is shown a cross-section of another embodiment of the invention comprising a top layer (1), a skin-contacting layer (4), preferably in the form of an skin-friendly adhesive, and a carbon dioxide generating layer (2). The carbon dioxide generating layer is in the form of a matrix in which micro capsules or particles of the carbon dioxide generating chemical composition is dispersed. The matrix may be a foam, alginate, hydrocolloid, polymer gel, hydrogel or the like.

Figure 3 shows an embodiment of the invention seen from above in which the carbon dioxide generating part is in the form of discrete zones connected with capillary tubes. The device also comprises an adhesive framing (4) and may optionally comprise an absorbing part (3) in which the discrete zones of carbon dioxide generating compositions may be embedded. The device is covered with a top layer. When the absorbing part absorbs wound exudate, the zones will be activated gradually, as the liquid will be transported by the capillaries from zone to zone. In this way a sustained release of carbon dioxide will be obtained. Depending on the dimensions of the zones and capillaries and the degree of embedment in the skin-contacting layer, the release will be substantially constant or in peaks or pulses over the wear time of the device.

The principles of an electrochemical cell of the kind that may be used in a device according to the invention are shown in Figure 4. The cell basically comprises 2 electrodes (7, 8) and an electrolyte (9). The electrodes and the electrolyte is encased in a casing (10) which is gas permeable but liquid impermeable. The driving force is a battery (11), that may be connected through an electrical controller (12). Atmospheric air or a supplied gas mixture reacts at one electrode, producing one or more reactants which are carried through the electrolyte to the second electrode, where one or more of the former reactants produces the same gases as were extracted from the atmosphere, thereby concentrating the partial pressure of the specific gases.

In Figure 5 is shown an embodiment of the invention comprising a top layer (1), an adhesive framing (4), a skin-contacting layer (3) and a carbon dioxide generating part (13, 14). The carbon dioxide generating part comprises a gas-reservoir (13) and an electrochemical cell (14) producing the gas and delivering the gas into the gas-reservoir (13). The electrochemical cell is embedded in the top layer, rendering it possible to extract atmospheric gas from the surroundings, and yet lead the generated gas into the device.

In Figure 6 is shown a cross-section of an embodiment of the invention comprising a top film (1), adhesive framing (4), skin-contacting layer (3), gas-reservoir (13) and two electrochemical cells (14). These cells are located close to the edge of the device, not directly above the wound (15), but above the intact skin (16). In this way the electrochemical cell, which may be of a rather hard and stiff structure, will not give rise to an unwanted pressure impact to the wound.

Figure 7 is showing the same embodiment of the invention as in Figure 6, seen from above, with the electrochemical cells (14) on the side of the device, and the gas-reservoir above the wound.

In Figure 8 is shown yet another embodiment of the invention where the electrochemical cell (14) is located aside from the wound (15), leaving the gas-reservoir (13) and the skin-contacting layer (3) directly above the wound (15). The electrochemical cell (14) is embedded in a support matrix (17), such as a foam, serving

to stabilise the structure of the device as well as to serve as a pressure distributor.

In Figure 9 is shown a view from above of an embodiment of the invention wherein the electrochemical cell (14) is located at a distance from the wound-contacting part and the gas-reservoir (13). The gas generated in the cell is conducted to the gas-reservoir through a connector tube 18.

Figure 10 is showing an embodiment of the invention almost similar to the one shown in Figure 9, but with the difference that the electrochemical cell (14) is no longer an integral part of the device but only connected hereto by the connector tube (18). In this way the electrochemical cell will not give rise to problems with unwanted pressure impacts to the wound or the sensitive skin surroundings. The tube (18), may when not in use, be wound up around the electrochemical cell (14) as shown in Figure 11. In this embodiment the electrochemical cell may be worn e.g. at the belt, while the device is applied to the leg.

CLAIMS

1. A device for treating a skin site or for promotion of healing of a wound site at an exposed surface of the skin of a human being by providing carbon dioxide at the exposed surface of said skin site or wound, said device comprising a top layer, means for generating carbon dioxide in situ and a skin-contacting layer.

2. A device according to claim 1 characterised in that the carbon dioxide-generating means comprises means for controlling the gas generation.

3. A device according to any of claims 1 - 2 characterised in that the generation of carbon dioxide is extended over a period of time.

4. A device according to any of claims 1 - 2 characterised in that the carbon dioxide is delivered discontinuously or in peaks or pulses.

5. A device according to any of claims 1 - 4 characterised in that the skin-contacting layer comprises an absorbing material, such as a foam, alginate, polymer gel, hydrogel or hydrocolloid.

6. A device according to any of claims 1 - 5 characterised in that the top layer is substantially impermeable to carbon dioxide.

7. A device according to any of claims 1 - 6 characterised in that the skin-contacting layer comprises an adhesive.

8. A device according to any of claims 1 - 7 characterised in that the CO_2-generating means comprises at least one chemical composition being capable of generating carbon dioxide when activated.

9. A device according to any of claims 1 - 7 characterised in that the carbon dioxide-generating means generates carbon dioxide electrochemically.

10. A device according to claim 9 characterised in that the carbon dioxide-generating means both generates carbon dioxide and oxygen and/or NO_x.

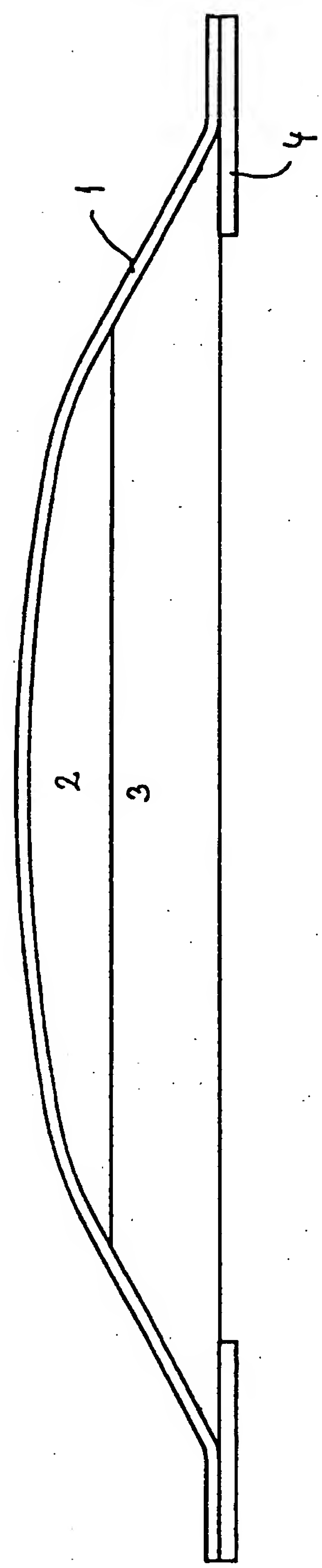

Fig. 1

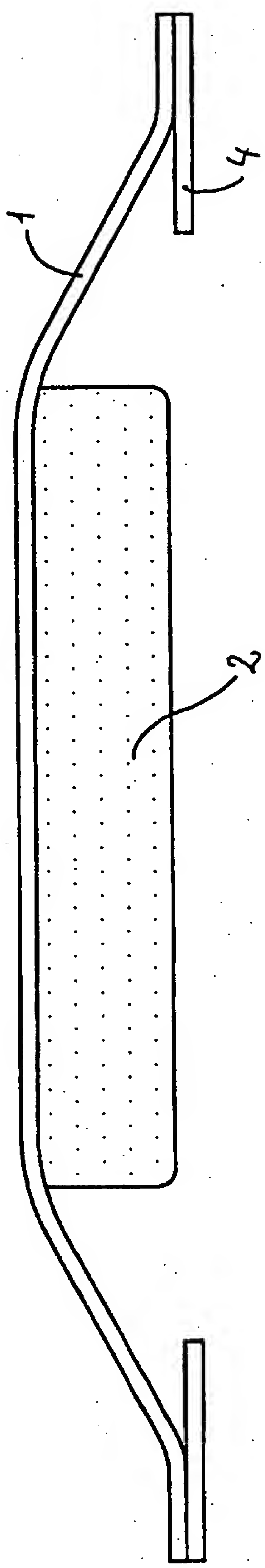

Fig. 2

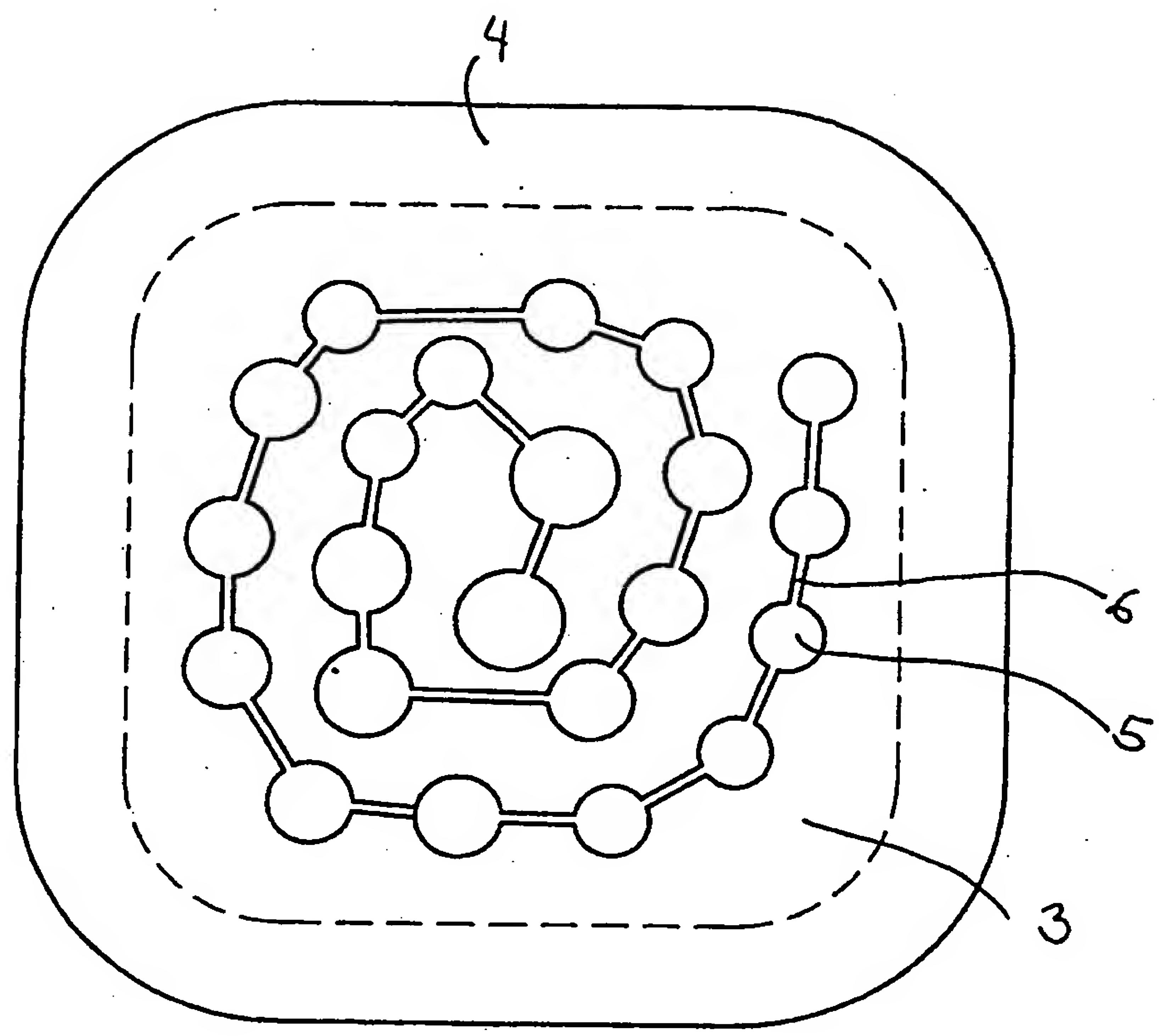

Fig. 3

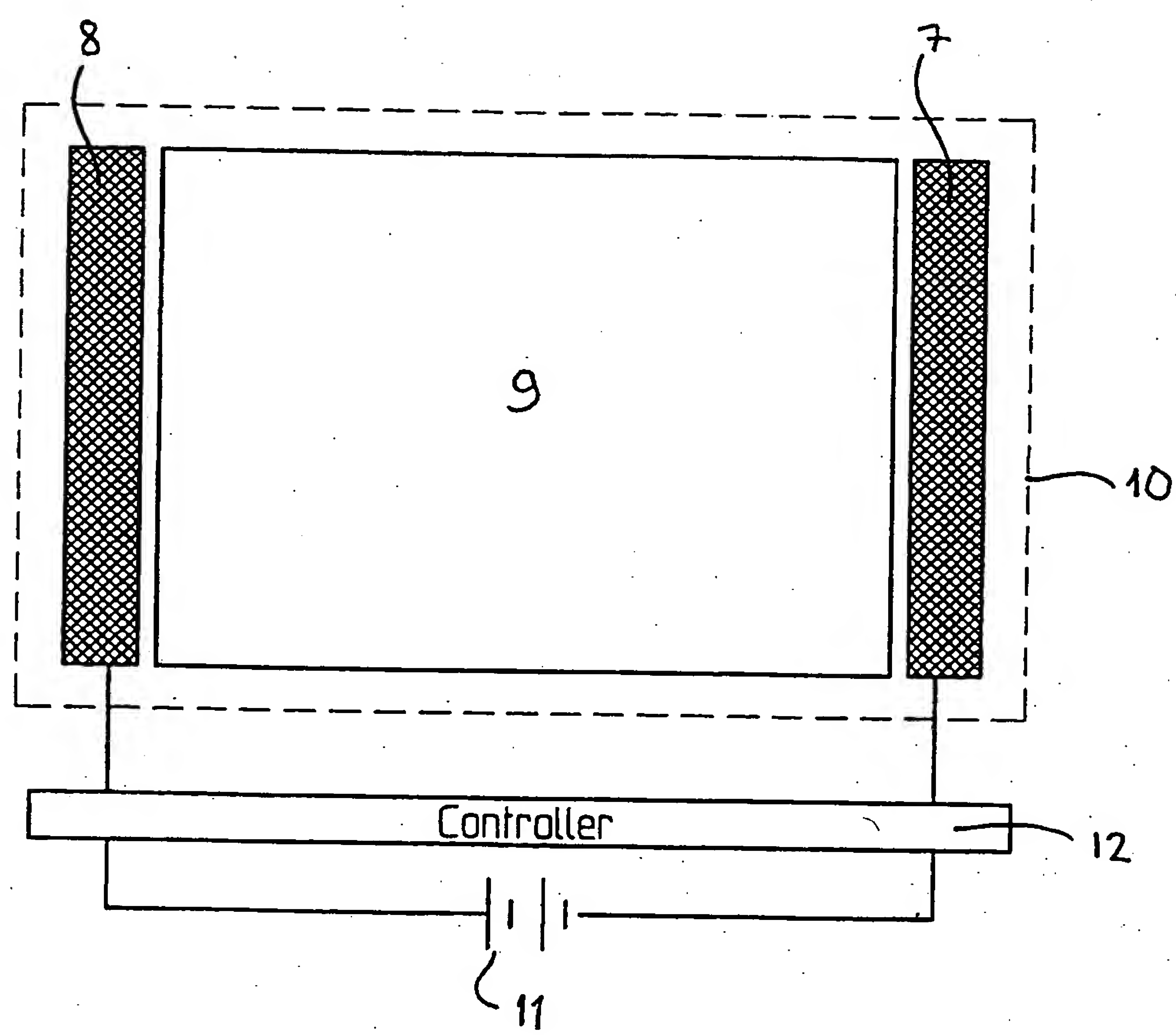

Fig. 4

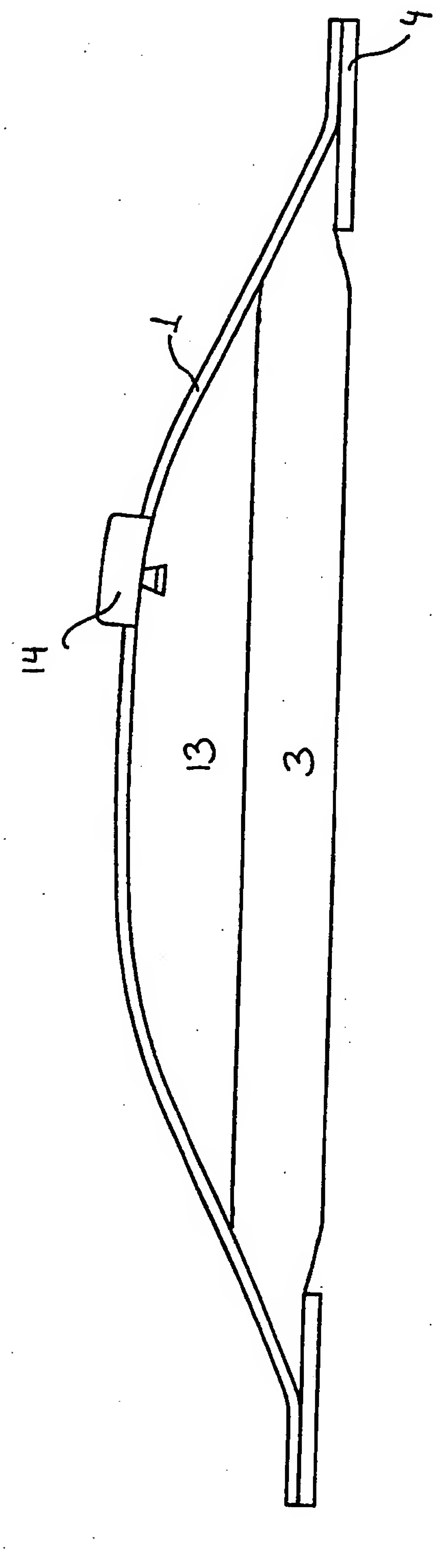

Fig. 5

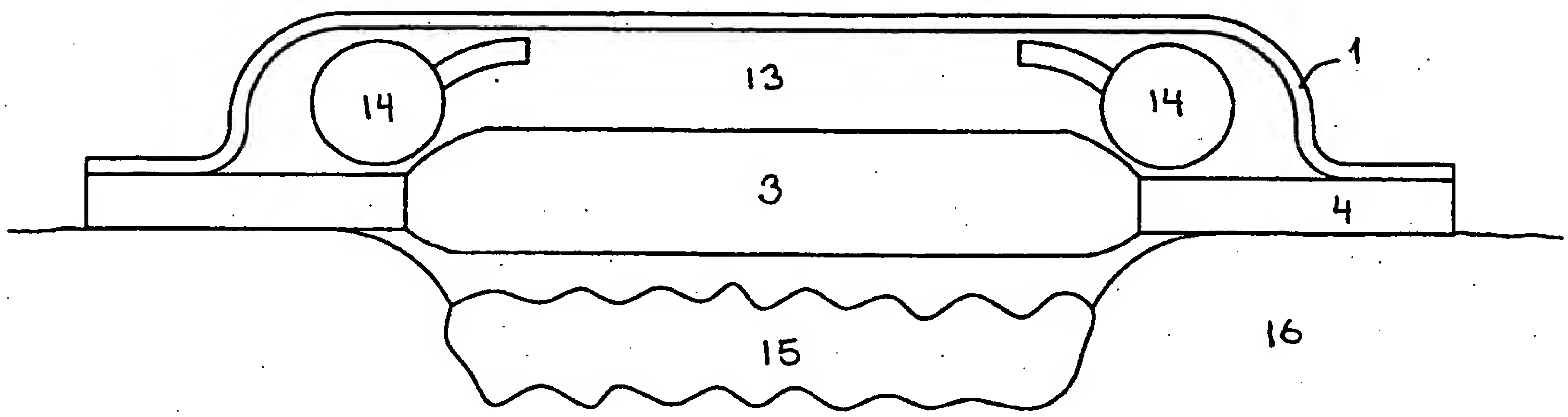

Fig. 6

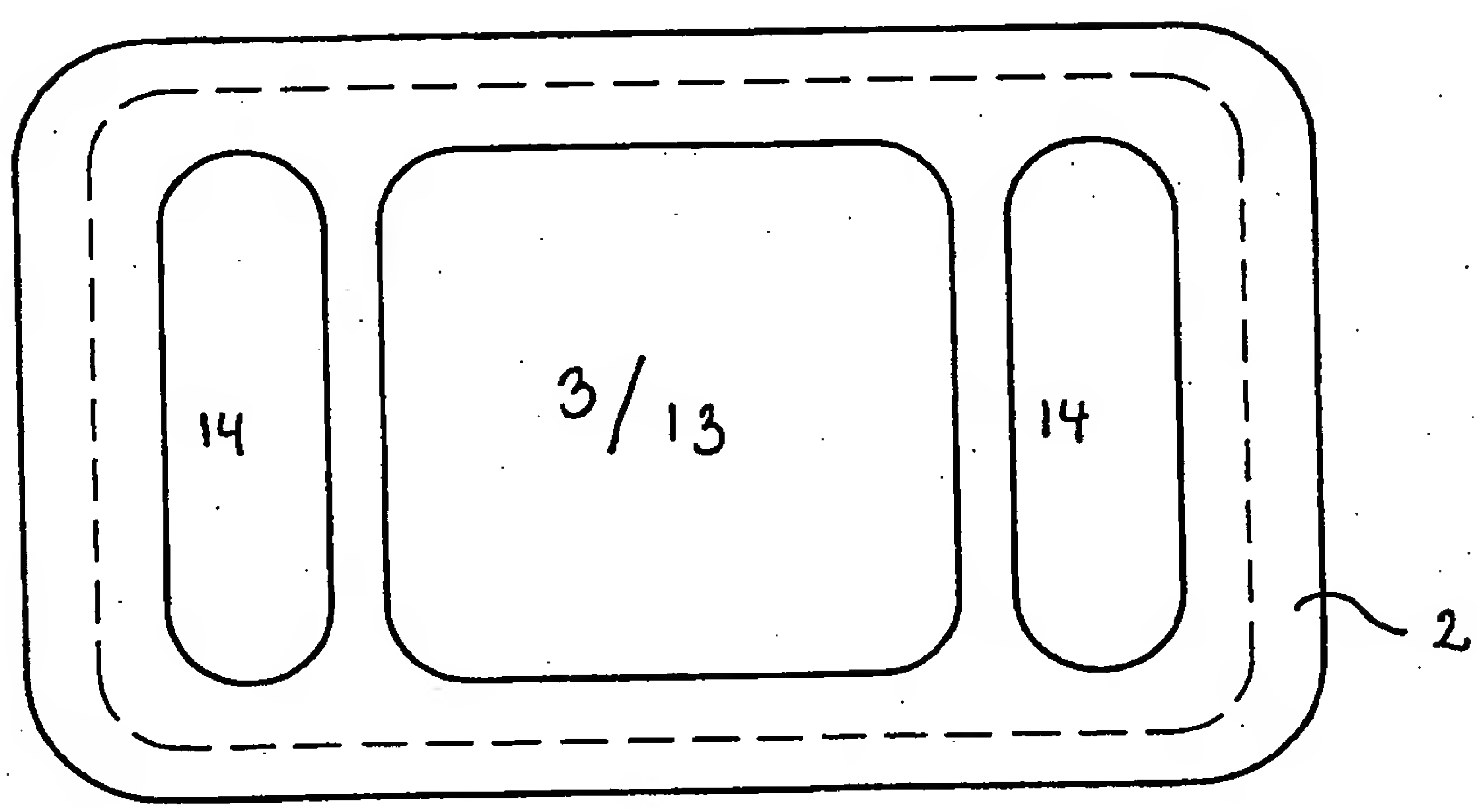

Fig. 7

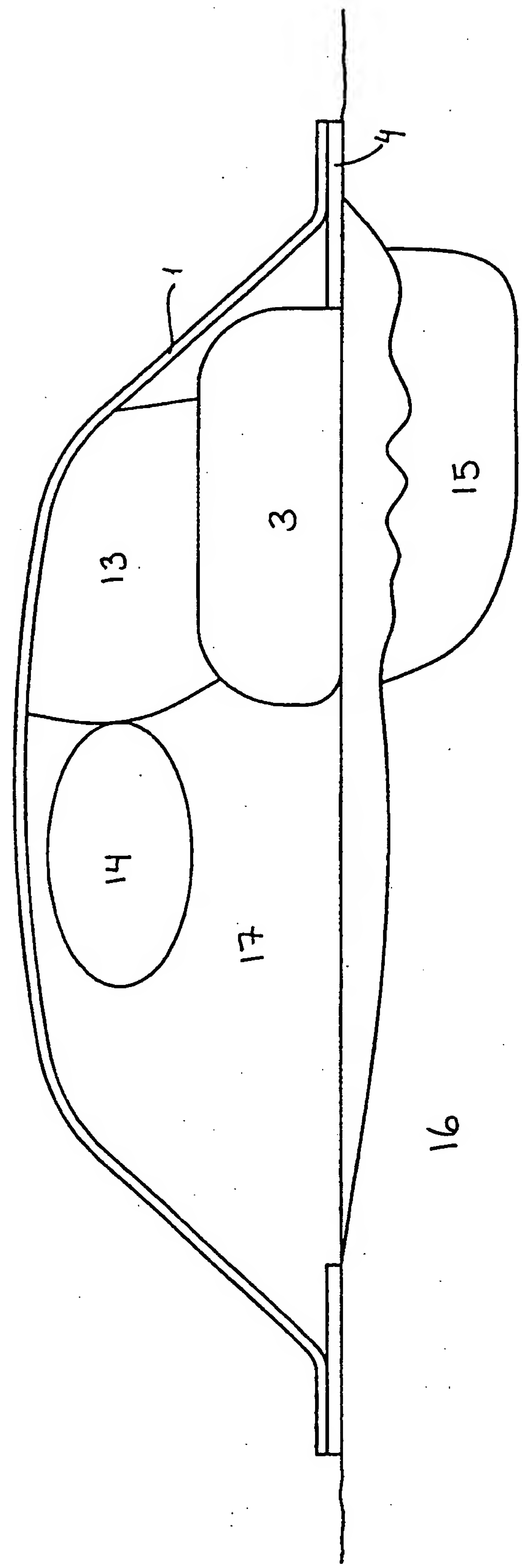

Fig. 8

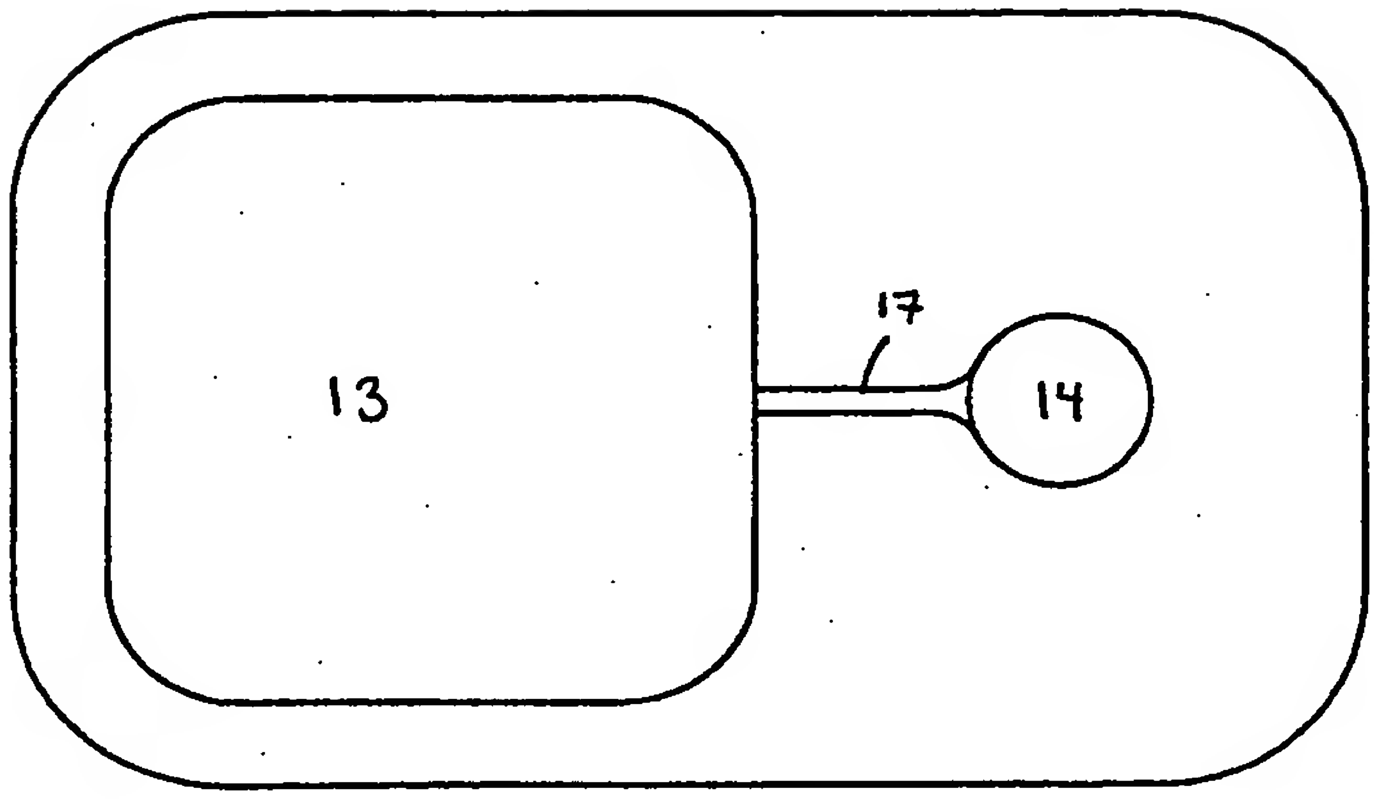

Fig. 9

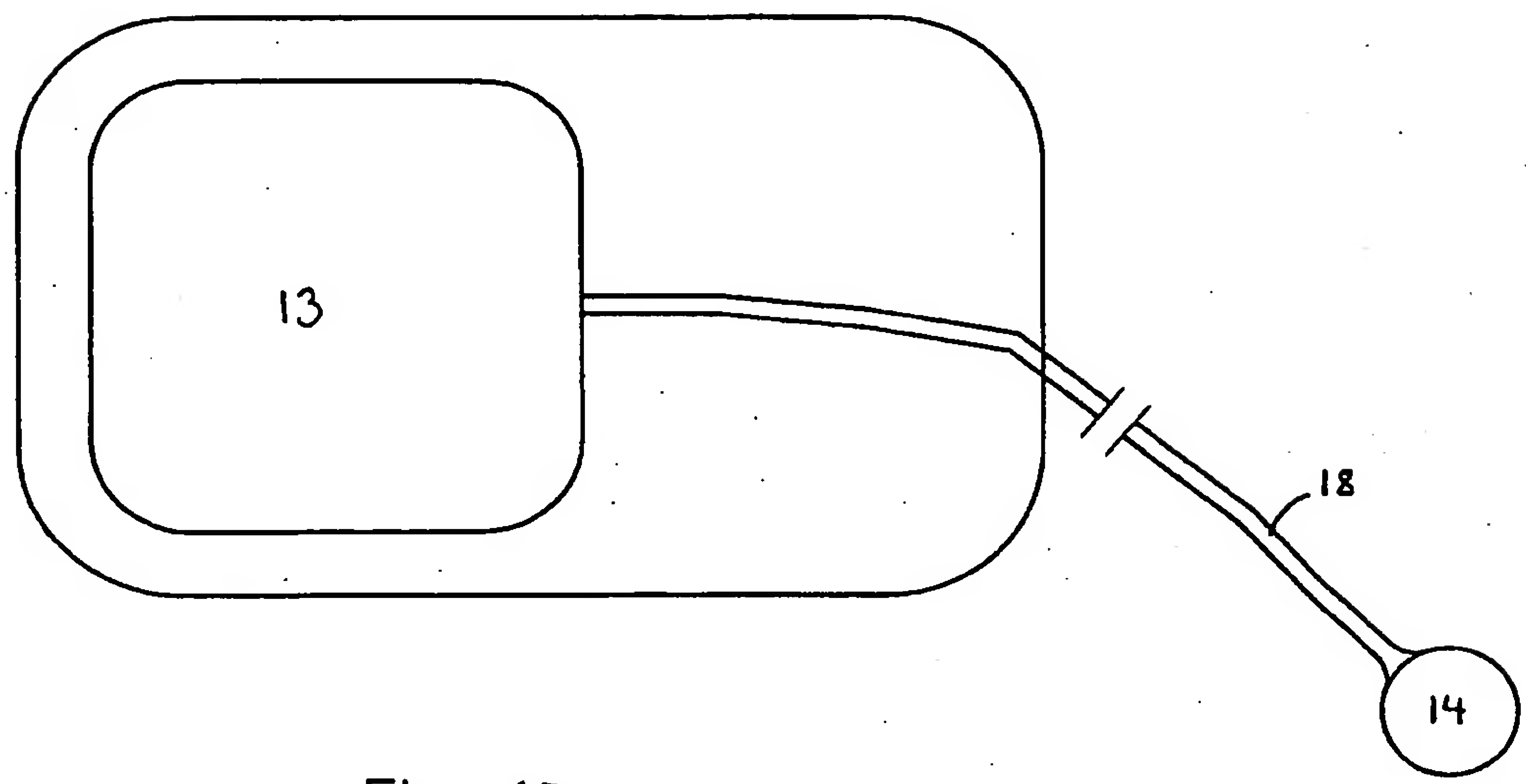

Fig. 10

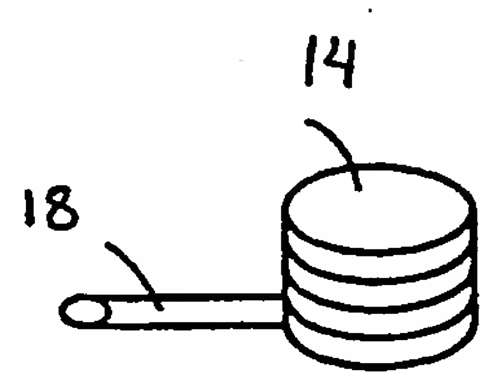

Fig. 11